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10/634,049

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Jose Luis Francese

MED-015

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SUITE 407

STAMFORD, CT 06902

EXAMINER

NGUYEN, TUAN VAN

ART UNIT

PAPER NUMBER

3731

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |  |  |
|------------------------------|--------------------------------------|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/634,049 | <b>Applicant(s)</b><br>FRANCESE ET AL. |  |
|                              | <b>Examiner</b><br>TUAN V. NGUYEN    | <b>Art Unit</b><br>3731                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,5-32 and 43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,5-32 and 43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Claims 1, 5-32 and 43 are pending in this present application.
2. In previous Office action, claims 1, 5-32 and 43 were examined and rejected.

### ***Response to Amendment***

3. Applicant's arguments filed on March 5, 2008 have been fully considered but they are moot in view of new ground of rejection.

### ***Claim Objections***

4. Claim 1 is objected to because of the following informalities: line 4 recites the limitation of "though" is unclear. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action  

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
7. **Claims 1, 5-9, and 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Collett (US 3,717,151) in view of Aboul-Hosn et al. (US 6,814,713).**
8. Collett discloses (Figs. 1-6) an surgical port device 10 for insertion through a body wall, comprising: cannula assembly 14 including a passageway, proximal end and distal end; flexible fingers 24 disposed at the distal end of the cannula assembly; cylindrical elongated member 12 having conical tapered tip 16 at its distal end; and retention 38 (col. 3, line 5 to col. 5, line 21). Collet discloses the invention substantially as claimed except for the fingers is in a form of an annular flange. However, Aboul-Hosn et al. disclose (see Figs. 1-5) an surgical port device 10 for insertion through a body wall, comprising: a cylindrical elongated member 14, which made of polymer or stainless steel, includes a tubular section having a distal end and a flexible flange 26 disposed at said distal end (Fig. 2); a valve assembly 20 at the proximal end of cylindrical member 14; and a insufflation port 12 in fluid communication with the passageway (see Fig. 3; col. 3, lines 35-55). Apparently, the advantage of the annular flange is for preventing unwanted ingress or egress into or out of the body cavity (col. 4, lines 28-27). It would have been obvious to one of ordinary skill in the art to add the flexible flange of Aboul-Hosn to the fingers of Collett or modify the width of the finger 24 to become an annular flange so that it

too would have the same advantage and incorporate the proximal valve and insufflation port as disclosed by Aboul-Hosn into the device of Collett to further utilize the device of Collett into the field of endoscopic surgery.

9. Referring to **claim 13**, the modified device of Collett fails to disclose the flange is made from a hydrophobic material. However, in endoscopic surgery, flange is made from a hydrophobic material is old and well known in the art. Therefore, it would have been obvious to make the flange of Collet device from a hydrophobic material. Extrinsic evidence, Aboul-Hosn et al. (US 6,228,063) discloses flexible flange 22, wherein the flange is made from silicone material. Noting that silicone is a hydrophobic material.
10. **Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Collett in view of Aboul-Hosn et al. as applied to claim 1 above and further in view of Freitas et al. (U.S. 5,330,497).**
11. The modified device of Collett disclose the invention substantially as claimed except for the cylindrical elongated member 12 has plurality of grooves on the outer surface that mating with the retention member wherein the grooves resists the retention member sliding in a proximal direction. Freitas discloses (see Figs 8, 9, and 10) a locking trocar sleeve having retention member 72 and the cylindrical elongated member 170 has plurality of grooves on the outer surface that mating with the retention member wherein the grooves resists the retention member sliding in a proximal direction (see col. 7, lines 9-45). Since it has been held that substitution of one known element with another to obtain predictable results is old

and well known in the art, therefore, it would have been obvious to one of ordinary skill in the art to incorporate the retention member of Collett with the retention member of Freitas to eliminate the suture.

12. **Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Collett in view of Aboul-Hosn et al. as applied to claim 1 above and further in view of Loeffler (U.S. 2,064,435).**
13. The modified device of Collett discloses the invention substantially as claimed except for the tubular member having at least one window therein. Loeffler discloses a technique for reinforcement of a molded article wherein the reinforcement having plurality of holes for facilitate the flow of molding composition through (see page 1, lines 42-50). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made by the applicant to use the molding technique, as disclosed by Loeffler, to incorporate into the device, as disclosed by Collett to gain the advantages as suggested by Loeffler. Here it is noted that a comparison of the recited process with the prior art processes does NOT serve to resolve the issue concerning patentability of the product. In re Fessman, 489 F2d 742, 180 U.S. P.Q. 324 (CCPA 1974). Whether a product is patentable depends on whether is known in the art or it is obvious, and is not governed by whether the process by which it is made is patentable. In re Klug, 333 F2d 905, 142 U.S.P.Q 161 (CCPA 1964). In an ex parte case, product-by-process claims are not construed as being limited to the product formed by the specific process recited. In re Hirao et al., 535 F2d 67, 190 U.S.P.Q. 15, see footnote 3.

14. Referring to claim 12, it is old and well known in the art that the distal end of the cannula is turned inward for facilitating the insertion of the cannula into a small incision in the body. It would have been obvious to modify the distal end of the cannula of Collett to have this feature so that it too would have the same advantage.
15. **Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Collett in view of Aboul-Hosn et al. as applied to claim 1 above and further in view of Waldron (US 6,626,942).**
16. The modified device of Collett discloses the invention substantially as claimed except for the flexible flange includes an annular projection that projects radially outward from the outer surface of the flexible flange. However, Waldron discloses a vaginal cup includes plurality of lips or annular projections 18, 19, and 22 (Figs. 1-2). Apparently, the design intended of the lips is for reinforcing the cup from collapsing and hindering flexibility after the device has been installed (col. 1, line 73 to col. 2, line 3). Further, Waldron discloses that because the lip is resiliently reinforced to hinder flexibility after the device has been installed, thereby, the wall thickness of the cup can be reduced, thereby, reducing the cost of the article (col. 2, lines 10-20). It would have been obvious to one of ordinary skill in the art to incorporate the lips as disclosed by Waldron to the outer surface of the modified annular flange of Collett so that it too would have the same advantage.

17. **Claims 19, 20-24, 28-32, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Collett (US 3,717,151) in view of Aboul-Hosn et al. (US 6,814,713) further in view of Waldron (US 6,626,942).**
18. As established in the rejection of claims 1 and 13-17 above, the modified device of Collett discloses the invention substantially as claimed except for the outer surface of the flange includes an annular projection that projects radially outward from the outer surface of the flexible flange. However, Waldron discloses a vaginal cup includes plurality of lips or annular projections 18, 19, and 22 (Figs. 1-2).  
Apparently, the design intended of the lips is for reinforcing the cup from collapsing and hindering flexibility after the device has been installed (col. 1, line 73 to col. 2, line 3). Further, Waldron discloses that because the lip is resiliently reinforced to hinder flexibility after the device has been installed, thereby, the wall thickness of the cup can be reduced, thereby, reducing the cost of the article (col. 2, lines 10-20). It would have been obvious to one of ordinary skill in the art to incorporate the lips as disclosed by Waldron to the outer surface of the flexible annular flange of Collett so that it to would have the same advantage.
19. **Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Collett in view of Aboul-Hosn et al. and Waldron as applied to claim 20 above and further in view of Freitas et al. (U.S. 5,330,497).**
20. The modified device of Collett discloses the invention substantially as claimed except for the cylindrical elongated member 12 has plurality of grooves on the outer surface that mating with the retention member wherein the grooves resists



the retention member sliding in a proximal direction. However, Freitas discloses (see Figs 8, 9, and 10) a locking trocar sleeve having retention member 72 and the cylindrical elongated member 170 has plurality of grooves on the outer surface that mating with the retention member wherein the grooves resists the retention member sliding in a proximal direction (see col. 7, lines 9-45). Since it has been held that substitution of one known element with another to obtain predictable results is old and well known in the art, therefore, it would have been obvious to one of ordinary skill in the art to incorporate the retention member of Collett with the retention member of Freitas to eliminate the suture.

21. **Claims 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Collett in view of Aboul-Hosn et al. and Waldron as applied to claim 19 above and further in view of Loeffler (U.S. 2,064,435).**
22. The modified device of Collett discloses the invention substantially as claimed except for the tubular member having at least one window therein. Loeffler discloses a technique for reinforcement of a molded article wherein the reinforcement having plurality of holes for facilitate the flow of molding composition through (see page 1, lines 42-50). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made by the applicant to use the molding technique, as disclosed by Loeffler, to incorporate into the device, as disclosed by Aboul-Hosn et al. to gain the advantages as suggested by Loeffler. Here it is noted that a comparison of the recited process with the prior art processes does NOT serve to resolve the issue concerning patentability of the

product. In re Fessman, 489 F2d 742, 180 U.S. P.Q. 324 (CCPA 1974). Whether a product is patentable depends on whether is known in the art or it is obvious, and is not governed by whether the process by which it is made is patentable. In re Klug, 333 F2d 905, 142 U.S.P.Q. 161 (CCPA 1964). In an ex parte case, product-by-process claims are not construed as being limited to the product formed by the specific process recited. In re Hirao et al., 535 F2d 67, 190 U.S.P.Q. 15, see footnote 3.

23. Referring to claim 27, it is old and well known in the art that the distal end of the cannula is turned inward for facilitating the insertion of the cannula into a small incision in the body. It would have been obvious to modify the distal end of the cannula of Collett to have this feature so that it too would have the same advantage.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TUAN V. NGUYEN whose telephone number is (571)272-5962. The examiner can normally be reached on M-F: 9:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/T. V. N./

Examiner, Art Unit 3731

/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3731